

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
James L. Madara et al.

Serial No.: 10/762,388

Filed: January 22, 2004

For: **MODULATION OF INFLAMMATION
RELATED TO COLUMNAR EPITHELIA**

Group Art Unit: 1612

Examiner: Fay, Zohreh A.

Atty. Dkt. No.: BWHI-029/US3

Confirmation No.: 4854

RESPONSE TO ADVISORY ACTION OF JANUARY 19, 2011

Mail Stop AF

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

CERTIFICATE OF ELECTRONIC TRANSMISSION
37 C.F.R. § 1.8

I hereby certify that this correspondence is being electronically filed with the
United States Patent and Trademark Office via EFS-Web on the date below:

January 27, 2011 /Barbara A. Avery/

Date

Barbara A. Avery

Dear Sir:

This is in response to the Advisory Action dated January 19, 2011. In response to the requirements, enclosed is a copy of a Notice from the Board or Trustees of Applicant corporation providing for the authority of the Director of Corporate Sponsored Research to sign on behalf of Applicant and a copy of the assignment at Reel/Frame 007115/0098 with a recordation date of June 29, 1994.

It is believed that no fees are due in connection with this response. However, the Office is authorized to charge any fees associated with this response to Deposit Account 50-1212/BWHI-029/US3.

CUSTOMER NUMBER **38824**

Respectfully submitted,

/Scott D. Rothenberger/


Scott D. Rothenberger

Reg. No. 41,277

Attorney for Applicants

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
Phone: (612) 321-2801
Facsimile: (512) 536-4598

Date: January 27, 2011

Application Number 	Application/Control No. 10/762,388	Applicant(s)/Patent under Reexamination MADARA ET AL.	
Document Code - DISQ		Internal Document – DO NOT MAIL	

TERMINAL DISCLAIMER	<input type="checkbox"/> APPROVED	<input checked="" type="checkbox"/> DISAPPROVED
Date Filed : 10/29/10	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Felicia D. Roberts See TD Checklist for explanation

TERMINAL DISCLAIMER INFORMAL CHECKLIST

APPL. S.N.: 10/762,388

DATE:

EXAMINER:

ART UNIT:

PARALEGAL: /FELICIA ROBERTS/

MAIL ROOM DATE:

NUMBER OF TD(s) FILED: 1

INSTRUCTIONS: The paralegal has reviewed the submitted TD with the results as set forth below.

If you agree, please use the appropriate form paragraphs identified by this informal memo in your next Office action to notify applicant about the TD. If you disagree, please contact a QAS.

THIS CHECKLIST IS AN INFORMAL, INTERNAL CHECKLIST ONLY. IT MUST NOT BE MAILED TO APPLICANT. IT WILL BE SOFT SCANNED AND NOT VIEWABLE TO THE PUBLIC.

- ☐ The TD is PROPER and has been accepted and recorded. (See FP 14.23.)
- ☒ The TD is NOT PROPER and has not been accepted for the reason(s) checked below. (See FP 14.24.)
- ☐ The disclaimer fee under 37 CFR 1.20(d) in the amount of \$ has not been submitted, nor is there any pre authorization in the application to charge to a deposit account. (See FP 14.24 and 14.26.07.)
- ☐ The LIE has not processed fee for TD (the Paralegal should ask LIE to process the fee).
- ☐ The TD does not satisfy 37 CFR 1.32(b) (3) in that the person who signed the TD has not stated either: (a) the extent of his/her ownership interest, or (b) the extent of the business/organization entity's ownership interest on whose behalf the person signed. (See FPs 14.26 and 14.26.01.)
- ☐ The TD lacks the – enforceable only during the period of common ownership – clause needed to overcome a double patenting 37 CFR 1.321(c). (See FP 14.27.01).
- ☐ The TD lacks 37 CFR 1.321(d) statement for joint research agreement under 35 U.S.C. 103(c) (2) & (3). It doesn't include the waiver and enforceability provisions of 37 CFR 1.321(d). (See FP 14.27.011.)
- ☐ TD is directed to a particular claim(s); this is not acceptable, since the disclaimer must be of a terminal portion of the entire patent to be granted, MPEP 1490. (See FPs 14.26 and 14.26.02).
- ☐ The person who signed the terminal disclaimer:
- ☐ failed to state his/her capacity to sign for the business/organization entity. (See FP 14.28.)
- ☐ is not recognized as an officer of the assignee. (See FP 14.29.)
- ☐ does not have power of attorney, and thus, is not of record. (See FP 14.29.01.)

(Note: PoA can be given to a customer number, wherein all practitioners listed under the customer number have PoA. If PoA is established by a list of practitioners, the list may not comprise more than 10 practitioners. A representative of the assignee, who is not of record, cannot sign the TD unless it is established that the representative is a party authorized to act on behalf of the assignee.)

- ☒ The TD is not supported by evidence of chain of title to the assignee signing the TD due to a failure to submit either: (a) documentary evidence of a chain of title from the original inventor(s) to the assignee and a statement affirming that the documentary evidence was, or concurrently is being, submitted for recordation; or (b) the reel and frame number(s) where such documentary evidence is recorded in the Office. 37 CFR 3.73(b). (See FPs 14.30 and 14.34)

NOTE: This documentary evidence or the specifying of the reel and frame number may be found in the TD or in a separate paper submitted by applicant.)

- ☐ The TD is not supported by adequate evidence of chain of title to the assignee signing the TD, because the person who signed the submission under 37 CFR 3.73(b):
 - ☐ has failed to state his/her capacity to sign for the business entity. (See FPs 14.30.02 and 14.16.02
 - ☐ is not recognized as an officer of the assignee. (See FP 14.30.02 and 14.16.03)

(Note: On the submission under 37 CFR 3.73(b), the signature of an attorney or agent registered to practice before the Office is not sufficient, unless the attorney or agent is authorized to act on behalf of the assignee.)

- ☐ The TD is not signed (See FPs 14.26 and 14.26.03)
- ☐ The serial number of the application (or the number of the patent) which forms the basis for the double patenting is not identified (i.e., missing or incorrect) in the TD. (See FP 14.32)
- ☐ The serial number of the application being examined (or the number of the patent under reexam or reissue) is not identified or incorrect. (See FPs 14.26 and 14.26.04 or 14.26.05)
- ☐ The TD is not signed by all owners. See FPs 14.26 and 14.26.06.
- ☐ The period disclaimed is incorrect or not specified. (See FPs 14.24, 14.27.02 or 14.27.03)
- ☐ Other

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TERMINAL DISCLAIMER UNDER 37 CFR § 1.321

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

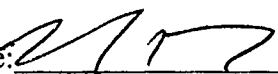
Dear Sir:

The owner, The Brigham and Women's Hospital, Inc., of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. § 154 and 173, as presently shortened by any terminal disclaimer, of prior US. Patent Application No. 11/838,046. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the above listed patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assignees.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. § 154 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR § 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of **The Brigham and Women's Hospital, Inc.**

Date: 8/20/10

Signature: 

Name:

Title:

Richard Stevens
Director, IP Management Group
Research Ventures & Licensing

08/268,049

MODULATION OF INFLAMMATION RELATED TO COLUMNAR EPITHELIA

01-27-

2011:13:32:14

Patent Assignment Abstract of Title

Total Assignments: 1**Application #:** 08268049**Filing Dt:** 06/29/1994**Patent #:** 5650435**Issue Dt:** 07/22/1997**PCT #:** NONE**Publication #:** NONE**Pub Dt:****Inventors:** JAMES L. MADARA, CHARLES N. SERHAN, SEAN P. COLGAN**Title:** MODULATION OF INFLAMMATION RELATED TO COLUMNAR EPITHELIA**Assignment: 1****Reel/Frame:** 007115 / 0098**Received:****Recorded:** 08/30/1994**Mailed:** 10/03/1994**Pages:** 3**Conveyance:** ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).**Assignors:** MADARA, JAMES L.**Exec Dt:** 08/12/1994

SERHAN, CHARLES N.

Exec Dt: 08/12/1994

COLGAN, SEAN P.

Exec Dt: 08/12/1994**Assignee:** BRIGHAM & WOMEN'S HOSPITAL
75 FRANCIS STREET
BOSTON, MASSACHUSETTS 02115**Correspondent:** LAHIVE & COCKFIELD

BETH E. ARNOLD

SUITE 510

60 STATE STREET

BOSTON, MA 02109

Search Results as of: 01/27/2011 13:32:09 PM

Disclaimer:**Assignment information on the assignment database reflects assignment documents that have been actually recorded.****If the assignment for a patent was not recorded, the name of the assignee on the patent application publication or patent may be different.****If you have any comments or questions concerning the data displayed, contact OPR / Assignments at 571-272-3350**[Close Window](#)

THE BRIGHAM AND WOMEN'S HOSPITAL
BOARD OF TRUSTEES

JANUARY 28, 1998

VOTED: That the Vice President, Research Administration, the Director, Research Administration, the Senior Contract and Grant Administrator and the Director, Ventures of The Brigham and Women's Hospital, Inc. (the "Hospital") and the Vice President, Corporate Sponsored Research of Partners HealthCare System, Inc. are authorized to execute all agreements on behalf of the Hospital concerning corporate-sponsored clinical trials and population-based studies with sponsoring corporations or with patient enrollment centers, and that execution of any such document on behalf of the Hospital by the above individuals, either singly or collectively, shall be valid and binding upon the Hospital.

VOTED: That the Director, Ventures of The Brigham and Women's Hospital, Inc. (the "Hospital") and the Vice President, Corporate Sponsored Research of Partners HealthCare System, Inc. are authorized to execute all laboratory research agreements, license agreements, material transfer agreements and any other technology transfer agreements with corporations on behalf of the Hospital, and any documents relating to the filing or protection of any patent, copyright, trademark or other intellectual property interest of the Hospital and that execution of any such document on behalf of the Hospital by the above individuals, either singly or collectively, shall be valid and binding upon the Hospital.

AND

VOTED: That the Vice President, Research Administration and the Director, Research Administration of The Brigham and Women's Hospital, Inc. (the "Hospital") and the Vice President, Research Management of Partners HealthCare System, Inc. are authorized to execute any application for a grant, proposal for a contract, best and final offer, award acceptance or contract related to laboratory research, clinical trials and population-based research with any governmental agency or any tax-exempt organization on behalf of the Hospital, and that execution of any such document on behalf of the Hospital by the above individuals, either singly or collectively, shall be valid and binding upon the Hospital.



RESEARCH VENTURES & LICENSING
Partnering to Advance Health Care

Christopher H. Colecchi
Vice President

800 Boylston Street, Suite 1150
Boston, MA 02199
Direct Tel: (617) 278-1008
Fax: (617) 236-4906
E-mail: ccolecchi@partners.org
Website: www.partners.org/rvl

March 11, 2008

Christopher Clark, Esq.
Office of General Counsel
Partners HealthCare System, Inc.
50 Staniford Street
Boston, Massachusetts 02114

RE: Research Signature Authority

Dear Mr. Clark:

Under paragraph 5 of the July 27, 1999 "research signature authority letter" from Dr. James Mongan on behalf of The General Hospital Corporation ("GHC"), and paragraph 5 of the September 22, 1999 vote of the Executive Committee of the Board of Trustees of The Brigham and Women's Hospital, Inc. ("BWH") (GHC and BWH each individually referred to as "a Corporation"), I hereby make the following designations:

1. Each individual holding a position listed below is authorized to execute and deliver on behalf of the Corporation indicated below (a) any agreement that involves the transfer (including assignments and licenses), or the disclosure under terms of confidentiality, of technology, research data, inventions, patents, copyrights, and other intellectual or tangible research property interests of the Corporation; (b) any agreement that involves the transfer to the Corporation of biological or other materials or equipment to be used for research purposes at the Corporation, or the disclosure to the Corporation under terms of confidentiality of any technology, data, or other information of a third party; (c) any document relating to or required for the filing, registration, prosecution, reporting, issuance, maintenance, re-issuance, or re-examination of any patent, copyright, trademark or other intellectual property interest of the Corporation, and any license of such intellectual property interest to the United States government required by federal law or to a not-for-profit person or any other organization entitled to receive such intellectual property interest pursuant to a duly



BRIGHAM AND
WOMEN'S HOSPITAL



MASSACHUSETTS
GENERAL HOSPITAL

approved and executed grant to or agreement with the Corporation; (d) any document relating to the Corporation's interests in consulting services being provided to third parties by employees, Professional Staff members, or other agents of the Corporation; and (e) any documents related to and which are reasonably necessary for any of the foregoing, including documents involving the acquisition of equity or similar interests in commercial licensees of the Corporation's intellectual or tangible research property or commercial sponsors of research at the Corporation; provided that any such agreement or document does not commit or involve an unreimbursed expenditure of the Corporation's funds in excess of \$100,000:

On behalf of GHC:

Title

Vice President for Research Ventures and Licensing
Associate Director, Corporate Sponsored Research and Licensing
Team Leader/Project Manager, Corporate Sponsored Research and
Licensing, MGH

On behalf of BWH:

Title

Vice President for Research Ventures and Licensing
Associate Director, Corporate Sponsored Research and Licensing
Team Leader/Project Manager, Corporate Sponsored Research and
Licensing, BWH

2. Each individual holding a position listed below is authorized to execute and deliver on behalf of the Corporation indicated below (a) any agreement which obligates the Corporation to perform clinical research services sponsored or supported by a for-profit person or organization, regardless of the value of such services; and (b) any documents related to and which are reasonably necessary for any of the foregoing; provided that any such agreement or document does not commit or involve an unreimbursed expenditure of the Corporation's funds in excess of \$100,000:

On behalf of GHC and BWH:

Title

Vice President for Research Ventures and Licensing
Director, Corporate Sponsored Clinical Research
Senior Clinical Research Agreement Associate, Corporate Sponsored
Clinical Research
Clinical Research Agreement Associate I, Corporate Sponsored Clinical
Research
Clinical Research Agreement Associate II, Corporate Sponsored Clinical
Research

3. Each individual holding a position listed below is authorized to execute and deliver on behalf of the Corporation indicated below (a) any agreement with a for-profit person or organization which grants the Corporation support for, or involves collaboration relating to, laboratory (non-clinical) research; (b) any agreement that involves the transfer to the Corporation of biological or other materials or equipment to be used for research purposes at the Corporation, or the disclosure to the Corporation under terms of confidentiality of any technology, data, or other information of a third party; and (c) any documents related to and which are reasonably necessary for any of the foregoing; provided that any such agreement or document does not commit or involve an unreimbursed expenditure of the Corporation's funds in excess of \$100,000:

On behalf of GHC and BWH:

Title

Vice President for Research Ventures and Licensing

Director, Corporate Sponsored Clinical Research

Senior Clinical Research Agreement Associate, Corporate Sponsored
Clinical Research

Clinical Research Agreement Associate I, Corporate Sponsored Clinical
Research

Clinical Research Agreement Associate II, Corporate Sponsored Clinical
Research

On behalf of GHC:

Title

Associate Director, Corporate Sponsored Research and Licensing

Team Leader/Project Manager, Corporate Sponsored Research and
Licensing, MGH

Senior Case Manager, Corporate Sponsored Research and Licensing,
MGH

Case Manager II, Corporate Sponsored Research and Licensing, MGH

Senior Contracts Associate, Corporate Sponsored Research and Licensing

Contracts Associate II, Corporate Sponsored Research and Licensing

On behalf of BWH:

Title

Associate Director, Corporate Sponsored Research and Licensing

Team Leader/Project Manager, Corporate Sponsored Research and
Licensing, BWH

Senior Case Manager, Corporate Sponsored Research and Licensing,
BWH

Case Manager II, Corporate Sponsored Research and Licensing, BWH

Senior Contracts Associate, Corporate Sponsored Research and Licensing

Contracts Associate II, Corporate Sponsored Research and Licensing

This letter rescinds any previous designations made by the Vice President for Corporate Sponsored Research and Licensing of Partners, including but not limited to those made on November 6, 2000 and July 31, 2001. The designations made in this letter shall continue in full force and effect until rescinded in writing by the Vice President of Research Ventures and Licensing, or by the Trustees or President of The General Hospital Corporation and The Brigham and Women's Hospital, Inc.

Sincerely,

A handwritten signature in black ink, appearing to read 'CH Colecchi', with a large, sweeping loop at the end.

Christopher H. Colecchi
Vice President of Research Ventures
and Licensing

cc: Barbara Bierer, M.D.
Richard Bringhurst, M.D.
Gary Gottlieb, M.D.
Brent Henry, Esq.
Brian Hicks
Daniel K. Podolsky, M.D.
Peter Slavin, M.D.
Frances Toneguzzo, Ph.D.

Draft 10/16/96
October , 1996

Ernest M. Haddad, Secretary
The General Hospital Corporation
Trustees' House

Dear Mr. Haddad:

Pursuant to Sections 6.2 and 6.4 of the Bylaws of the Corporation, and the October 20, 1995 vote of the Board of Trustees of the Corporation I hereby make the following authorizations effective immediately:

1. The Senior Vice President for Administration and the Chief Financial Officer each is authorized to agree to, execute and deliver on behalf of the Corporation any commitment which obligates the Corporation to expend total funds not in excess of \$500,000, or to dispose of or furnish property or services valued not in excess of \$500,000.
2. Acting within his or her assigned area of responsibility, each individual holding the position listed below is authorized to agree to, execute and deliver on behalf of the Corporation any commitment which obligates the Corporation to expend total funds not in excess of, or to dispose of or furnish property or services valued not in excess of, the amount set forth below opposite his or her title.

<u>Title</u>	<u>Authorized Amount</u>
Senior Vice President for Operations and Chief Information Officer	\$500,000
All other Senior Vice Presidents	\$250,000
Vice President of Partners HealthCare System, Inc.	\$250,000
General Counsel	\$250,000
Vice President	\$250,000
Director of the Office of the President	\$250,000
Director of the Budget	\$250,000
Director of Primary Care and Associate Chief of Medicine	\$250,000
Director of Graduate Medical Education	\$250,000
Administrator for Pathology	\$250,000
Administrator for Radiology and Radiation Oncology	\$250,000

3. Acting within his or her assigned area of responsibility and provided that the commitment has been approved by the Trustees in the course of their action on any budget of the Corporation or otherwise or by a duly authorized committee of the Trustees, each

Ernest M. Haddad
October , 1996
Page 2

individual holding the position listed below is authorized to agree to, execute and deliver on behalf of the Corporation any commitment which obligates the Corporation to expend

total funds not in excess of \$500,000, or to dispose of or furnish property or services valued not in excess of \$500,000.

Title

Senior Vice President
General Counsel
Vice President
Director of Primary Care and Associate Chief of Medicine
Director of Graduate Medical Education
Administrator for Pathology
Administrator for Radiology and Radiation Oncology

4. Provided that the commitment has been approved by the Trustees in the course of their action on any budget of the Corporation or otherwise or by a duly authorized committee of the Trustees, the Corporate Director of Materials Management of Partners HealthCare System, Inc. is authorized to agree to, execute and deliver on behalf of the Corporation any commitment for the purchase of goods which obligates the Corporation to expend total funds not in excess of \$500,000, or to dispose of or furnish property or services valued not in excess of \$500,000,
5. Provided that the commitment has been approved by the Trustees in the course of their action on any budget of the Corporation or otherwise or by a duly authorized committee of the Trustees, each individual holding the position listed below is authorized to agree to, execute and deliver on behalf of the Corporation any lease or rental schedule which does not exceed five years in duration, and any other instrument necessary thereto, and any commitment for the purchase of equipment, goods or services, which obligates the Corporation to dispose of or furnish property or services valued not in excess of \$150,000, or to expend total funds not in excess of \$150,000.

Title

Director of Materials Management/Purchasing
Director of Corporate Contracts and Negotiation

Ernest M. Haddad
October , 1996
Page 3

6. Provided that the commitment has been approved by the Trustees in the course of their action on any budget of the Corporation or otherwise or by a duly authorized committee of the Trustees, and provided that they have been authorized in writing by the Corporate Director of Materials Management of Partners HealthCare System, Inc., each individual holding the position listed below is authorized to agree to, execute and deliver on behalf of the Corporation any lease or rental schedule which does not exceed five years in duration, and any other instrument necessary thereto, and any commitment for the purchase of equipment, goods or services, which obligates the Corporation to dispose of or furnish property or services valued not in excess of \$50,000, or to expend total funds not in excess of \$50,000.

Title

Purchasing Agent
Buyer

7.

Each individual holding the position listed below is authorized to execute and deliver on behalf of the Corporation (a) any agreement which obligates the Corporation to perform laboratory or clinical research services sponsored or supported by a for-profit person or organization, regardless of the value of such services; (b) any agreement that commits the Corporation to keep confidential information disclosed by a third party that relates to an actual or potential laboratory or clinical research services agreement sponsored or supported by a for-profit person or organization; and (c) any agreement that involves the disclosure under terms of confidentiality or the transfer (including assignments and licenses) of technology, research data, inventions, patents, copyrights, and other intellectual or tangible research property interests of the Corporation; provided that such document does not commit or involve an unreimbursed expenditure of the Corporation's funds in excess of \$100,000:

Title

Senior Vice President for Research and Technology
Vice President for Patents, Licensing and Industry Sponsored Research
Managing Director of the Office of Technology Affairs
Associate Director for Industry Agreements of the Office of Technology
Affairs
Assistant Director of the Office of Technology Affairs
Director for Proposal and Award Management
Financial Director for Grants and Contracts

Ernest M. Haddad
October , 1996
Page 4

8. Each individual holding the position listed below is authorized to execute and deliver on behalf of the Corporation (a) any document relating to or required for the filing, registration, prosecution, reporting, issuance, maintenance, re-issuance, or re-examination of any patent, copyright, trademark or other intellectual property interest of the Corporation; and (b) any license of such intellectual property interest to the United States government required by federal law or to a not-for-profit person or any other organization entitled to receive such intellectual property interest pursuant to a duly approved and executed grant to or agreement with the Corporation; provided that such document or license does not commit or involve an unreimbursed expenditure of the Corporation's funds in excess of \$100,000:

Title

Vice President for Patents, Licensing and Industry Sponsored Research
Managing Director of the Office of Technology Affairs
Associate Director for Patents of the Office of Technology Affairs

9. Each individual holding the position listed below is authorized to execute any grant application, award or agreement with any not-for-profit or governmental person or organization that obligates the Corporation to provide laboratory or clinical research services; provided that such document does not commit or involve an unreimbursed expenditure of the Corporation's funds in excess of \$100,000:

Title

Senior Vice President for Research and Technology
Director for Proposal and Award Management
Financial Director for Grants and Contracts
Research Grant and Contract Specialist

10. The Director of Social Services is authorized to agree to, execute and deliver on behalf of the Corporation any commitment involving publicly funded social service programs which obligates the Corporation to dispose of or furnish property or services valued not in excess of \$150,000.
11. The Vice President of Massachusetts General Physicians Organization, Inc. is authorized to agree to, execute and deliver on behalf of the Corporation non-tuition loans to resident members of the Professional Staff under \$10,000, secured or unsecured.

Ernest M. Haddad
October , 1996
Page 5

Each of the authorizations made on this date shall continue in full force and effect until rescinded in writing by the President or by the Trustees. I hereby rescind all authorizations made by the Chief Executive Officer or President prior to this date.

Sincerely,

James J. Mongan, M.D.
President

22049